REMARKS

Claims 1, 3, 4, 13, 14 and 17 are currently pending. Claim 1 is the only independent claim.

In the Office Action dated December 27, 2007, claim 1 was rejected as anticipated by U.S. Patent No. 6,540,725 to Ponzi, U.S. Patent No. 6,613,017 to Mickley, and U.S. Patent No. 6,616,626 to Crank et al. The Applicant respectfully requests reconsideration of these rejections in view of the above amendments and the following remarks.

Claim 1 as amended above recites an injection catheter comprising a first elongated shaft, a needle disposed within the first elongated shaft, and a stop collar also disposed within the first elongated shaft near the distal end of the needle. Claim 1 further recites a first set of threads located on the needle, and a second set of threads located on the stop collar. According to claim 1, "rotation of the needle within the first elongated shaft causes longitudinal movement of the stop collar relative to the needle within the first elongated shaft, the positioning of the stop collar within the first elongated shaft controlling a variable extent to which the needle may be extended beyond the distal end of the first elongated shaft."

An embodiment within the scope of claim 1 is illustrated in Applicant's Figure 3, shown below:

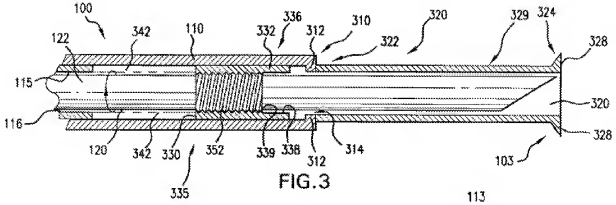

FIG.3

As described in the Applicant's Specification, the Figure 3 embodiment comprises a first elongate shaft 110 and a needle 120 disposed through the lumen 116. In accordance with this embodiment, the outer surface of the needle 120 is surrounded by and engaged with a needle depth control device 330, in the form of a stop collar. Needle depth control device or stop collar 330 has an inner surface with a thread 339 disposed thereon. A section of the outer surface of the needle 120 has a thread 352 that engages the thread 339 of the stop collar 330.

In the Figure 3 embodiment, the stop collar 330 has a plurality of longitudinal protrusions 332 that are slidingly disposed in an equal plurality of longitudinal grooves 342 disposed in an inner surface 115 of the first elongate shaft 110. This arrangement permits longitudinal movement of the stop collar 330 inside the first elongate shaft 110 along the longitudinal axis of catheter 100 but prevents rotational movement of the stop collar 330 within the first elongate shaft 110. Thus, rotation of the needle 120 causes longitudinal movement of the stop collar 330.

In the Figure 3 embodiment, the stop collar 330 limits the penetration depth of the needle 120 by contacting the proximal side of flange 312 of the first elongate shaft 110 when the needle 120 is urged toward the distal end 103 of the catheter. Therefore, an injection depth, that is, the distance needle 120 may be extended past distal end 324 of flared tip section 320, may be limited by setting stop collar 330 to a predetermined distance by rotation of the needle 120. For example, to set the injection depth to 5 mm past flared tip 328, stop collar 330 is set to travel only 5 mm before contacting the proximal side of flange 312. Although the predetermined distance may be selected at the proximal end of catheter 100, the distance is controlled at the distal end of catheter 100 by the stop collar 330.

The Applicant respectfully submits that the invention as claimed in claim 1 is patentable over the cited references.

The Ponzi reference discloses a catheter with a thumb control 106 that is located at the proximal end of the catheter. Such an arrangement has the drawback of not being able to compensate for changes of relative positioning between an inner needle and an outer shaft that can occur when the catheter is bent. In addition, the thumb control 106 is not located within an elongated shaft of the catheter, nor does it move longitudinally within an elongated shaft of the catheter. Moreover, the thumb control 106 is not in threaded contact with the needle such that rotation of the needle within the elongated shaft causes longitudinal movement of the thumb control 106 relative to the needle within the elongated shaft.

Accordingly, Ponzi does not meet several limitations of Applicant's claim 1. For example, Ponzi does not disclose or suggest "a stop collar disposed within the first lumen of the first elongated shaft near the distal end of the needle." Ponzi also does not disclose or suggest a first set of threads located on the needle and a second set of threads located on the stop collar, "wherein rotation of the needle within the first elongated shaft causes longitudinal movement of the stop collar relative to the needle within the first elongated shaft, the positioning of the stop collar within the first elongated shaft controlling a variable extent to which the needle may be extended beyond the distal end of the first elongated shaft."

The Mickley reference also does not disclose or suggest Applicant's invention as claimed in claim 1. The Office Action points to Figures 3 and 6-8 of Mickley.

In Figure 3 of Mickley, there is no adjustable stop collar at all. The first helical member 154 is fixed to the outer shaft. Turning the second elongate shaft advances the second elongate shaft within the outer shaft.

In Figure 6 of Mickley, the catheter includes a stop 478, but the positioning of this stop 478 cannot be adjusted by rotating the needle. In fact, in Figure 6 of Mickley, there are no

threads at all located on the needle. The threads associated with the stop 478 are located on the third elongate shaft 474, and they engage threads on the header 466. Thus, Figure 6 of Mickley does not disclose or suggest at least the features of claim 1 requiring "a first set of threads located on the needle" and corresponding threads located on the stop collar "wherein rotation of the needle within the first elongated shaft causes longitudinal movement of the stop collar relative to the needle within the first elongated shaft, the positioning of the stop collar within the first elongated shaft controlling a variable extent to which the needle may be extended beyond the distal end of the first elongated shaft."

Figures 7 and 8 of Mickley similarly do not disclose or suggest Applicant's invention. In those Figures there are again no threads at all located on the needle. The threads associated with the stop 578 are located on the third elongate shaft 574, and they engage threads on the ferrule 584. To adjust the positioning of the stop 578, the physician is required to remove the third elongate shaft 574 and ferrule 584 from the catheter and rotate the ferrule 584 relative to the third elongate shaft. (col. 10, lines 30-32). Thus, Figures 7 and 8 of Mickley do not disclose or suggest at least the features of claim 1 requiring "a first set of threads located on the needle" and corresponding threads located on the stop collar "wherein rotation of the needle within the first elongated shaft causes longitudinal movement of the stop collar relative to the needle within the first elongated shaft, the positioning of the stop collar within the first elongated shaft controlling a variable extent to which the needle may be extended beyond the distal end of the first elongated shaft."

In Applicant's invention, the physician does not need to withdraw any parts from the catheter to adjust the positioning of the stop collar, and the adjustments can simply be made by

rotating the needle. This can be done at the proximal end of the device by the physician, thereby causing adjustment of the stop collar at the distal end of the device.

The Crank reference also does not disclose or suggest the invention of claim 1. The Office Action cites Figures 1-3 and 10-12B of Crank. Figure 1-3 do not disclose a stop collar as claimed in claim 1. Figure 10 shown a catheter with an inner stop 294, but this inner stop 294 is fixed to the needle 288. (col. 9, lines 51-52). Turning the needle causes the inner stop 294 to rotate along with the needle, and by doing so the inner stop 294 can be turned to different angular positions corresponding to outer stops 295, 296 and 297. This is in contrast to Applicant's invention, which has a stop collar that is adjustable in position relative to the needle, and which also has a unique threaded engagement between the needle and stop collar such that rotation of the needle causes longitudinal adjustment of the stop collar as claimed. Thus, Crank is missing several features from Applicant's claim 1, including at least "a first set of threads located on the needle" and "a second set of threads located on the stop collar," as well as the claimed feature "wherein rotation of the needle within the first elongated shaft causes longitudinal movement of the stop collar relative to the needle within the first elongated shaft, the positioning of the stop collar within the first elongated shaft controlling a variable extent to which the needle may be extended beyond the distal end of the first elongated shaft."

For the foregoing reasons, the Applicant respectfully requests reconsideration of this application and allowance of the claims. Should any questions arise concerning this application, the Examiner is invited to contact the undersigned at (202) 220-4200. The Commissioner is authorized to charge any necessary fees or credit any overpayments under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

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